A Call to Action: Prevention and Early Detection of Colorectal Cancer (CRC)

5 Key Messages

- Screening reduces mortality from CRC
- All persons aged 50 years and older should begin regular screening
- High-risk individuals may need to begin screening earlier
- Colorectal cancer can be prevented
- Insufficient evidence to suggest a best test;

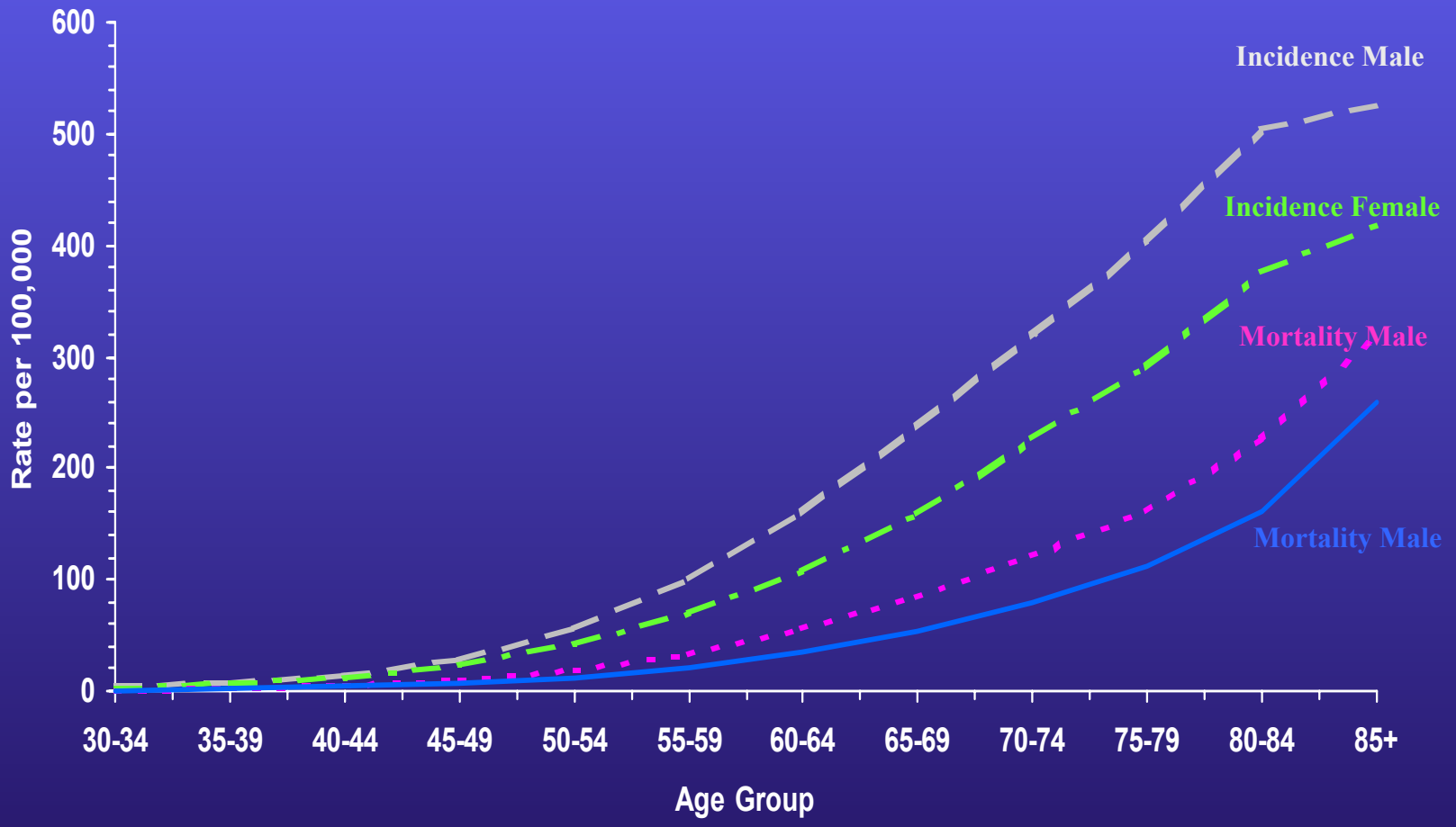
  any screening test is better than no screening test

Making the Case

Burden of Disease

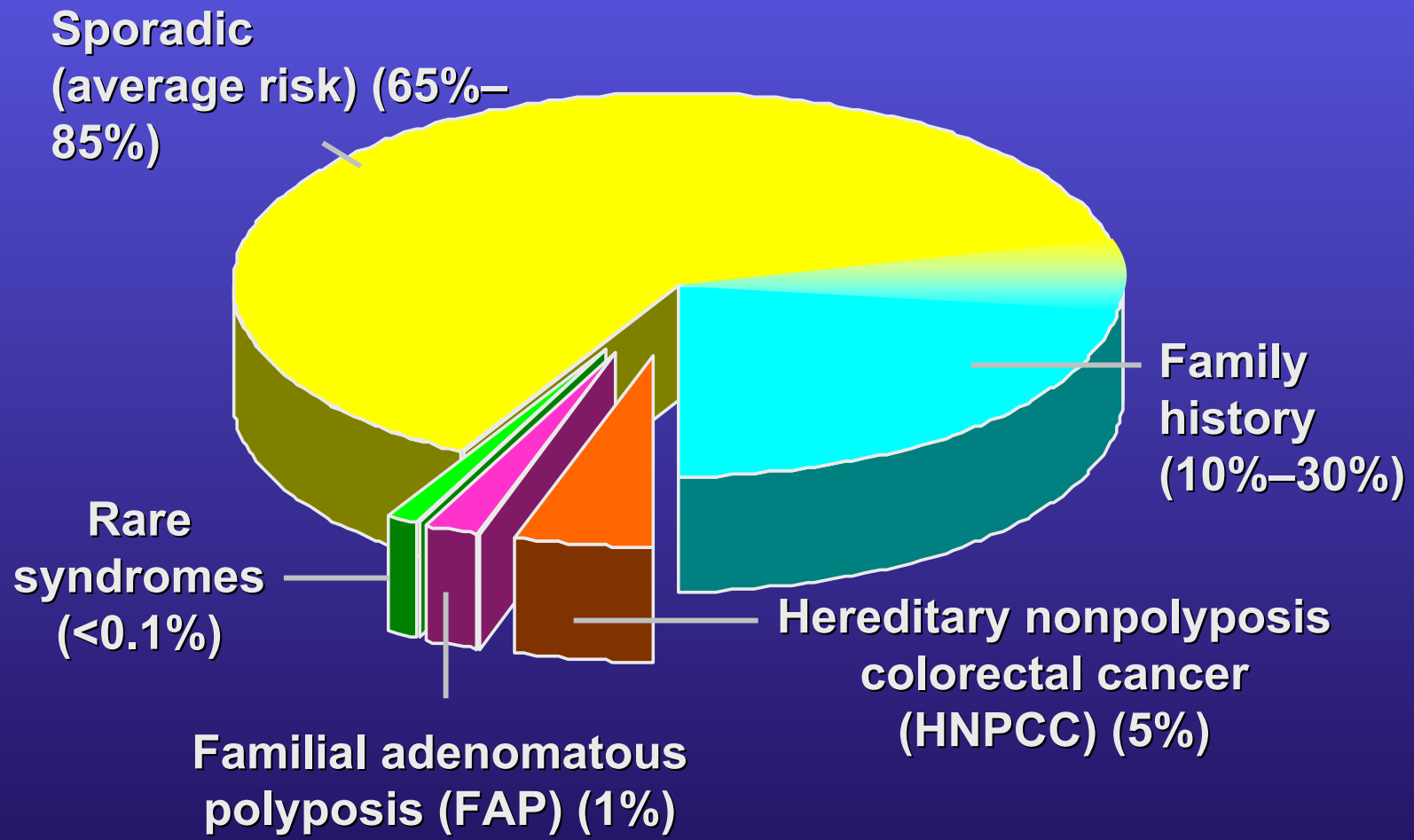
- Second leading cause of cancer death in US
- Both women and men
- All races
- American Cancer Society 2003 estimates:
  - 147,500 new cases
  - 57,100 deaths
- Treatment costs over $6.5 billion per year
  - Among malignancies, second only to breast cancer at $6.6 billion per year

Cancers of the Colon and Rectum (Invasive): Average Annual Age-Specific SEER Incidence and U.S. Mortality Rates By Gender, 1995-1999



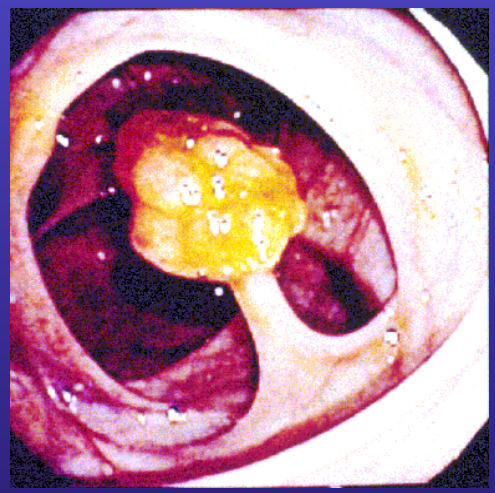
Source: SEER Cancer Statistics Review, 1973-1999

Colorectal Cancer (CRC)

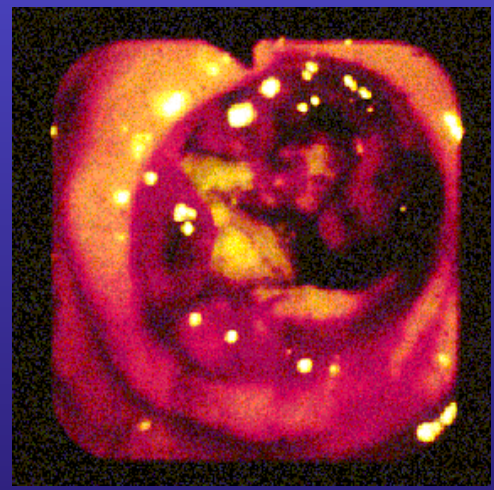


Natural History

Polyp



Advanced cancer



Screening=Prevention & Early Detection

Prevention = polyp removal 

Decreased Incidence

Early Detection 

Decreased Mortality

Colorectal Cancer Screening Guidelines for Average Risk Persons Age ≥ 50

- U.S. Preventive Services Task Force, 1996
  - Updated 2002
- American Cancer Society, 1997
  - Updated 2001
- Interdisciplinary task force, 1997
  - To be updated 2002

Screening Methods

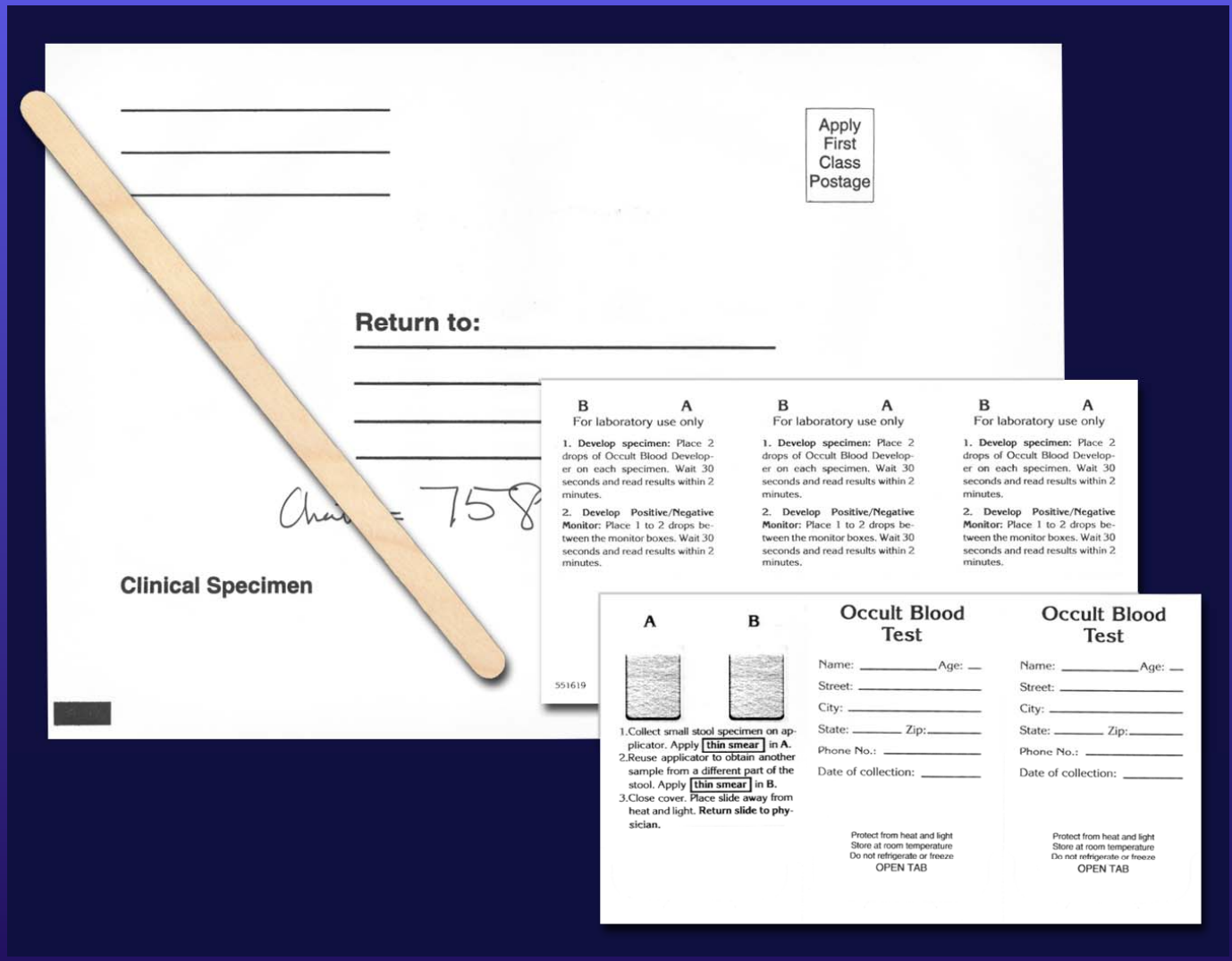
- Annual Fecal Occult Blood Test (FOBT)
- Flexible Sigmoidoscopy every 5 years
- Annual FOBT + Flexible Sigmoidoscopy every 5 years
- Colonoscopy every 10 years
- Double Contrast Barium Enema (DCBE) every 5 years

- *Insufficient evidence for "best" test*

FOBT testing

- Three-card at home FOBT
  - Supported by trial data (Mandel 1993, Hardcastle 1996, Kronburg 1996)
- In-Office FOBT (not recommended)
  - Commonly done in practice (Nadel, NHIS, 2002)
  - No studies on CRC incidence or mortality
  - Less sensitive

FOBT


Apply First Class Postage
Return to:
Clinical Specimen
B A
For laboratory use only
1. Develop specimen: Place 2 drops of Occult Blood Developer on each specimen. Wait 30 seconds and read results within 2 minutes.
2. Develop Positive/Negative Monitor: Place 1 to 2 drops between the monitor boxes. Wait 30 seconds and read results within 2 minutes.
551619
A B
1.Collect small stool specimen on applicator. Apply thin smear in A.
2.Reuse applicator to obtain another sample from a different part of the stool. Apply thin smear in B.
3.Close cover. Place slide away from heat and light. Return slide to physician.
Occult Blood Test
Name: Age:
Street:
City:
State: Zip:
Phone No.:
Date of collection:
Protect from heat and light
Store at room temperature
Do not refrigerate or freeze
OPEN TAB

FOBT: Evidence

	Minn, 1993	Minn, 1999	UK, 1996	Denmark, 1996
Frequency of Testing	Annual	Biennial	Biennial	Biennial
Duration (years)	18	18	8	13
Slide rehydration	Yes	Yes	No	No
% requiring colonoscopy	30%	30%	5%	5%
Mortality reduction	33%	21%	15%	18%
Incidence reduction	20%	17%		

FOBT: Implementation

- Preparation
- Periodicity
- Provider capacity
- Follow-up
  - Positive FOBT requires total colon exam
  - After a negative total colon exam, suspend annual FOBT for 5 to 10 years
  - Negative FOBT requires repeat FOBT in 1 year

To Begin a Home FOBT Screening Program

You will need

- FOBT card kits
- Assigned roles for office staff
  - Instructing and encouraging patients
  - Developing cards
  - Recording results
  - Notifying patient and clinician

FOBT: Counseling Your Patients

- Explain exactly what to expect
- Don't rely solely on instructions in kit
- Consider using a reminder system to increase adherence

Flexible Sigmoidoscopy

Fiberoptic sigmoidoscope

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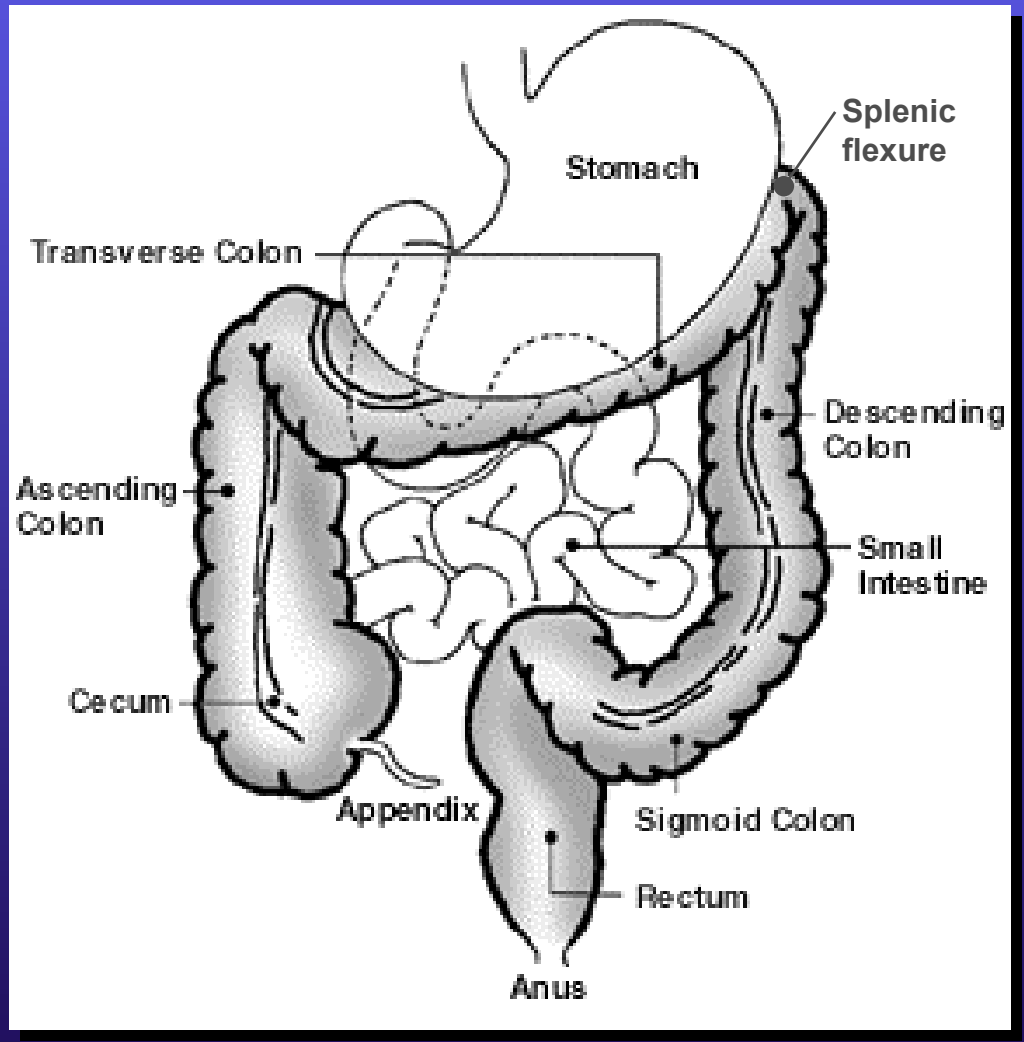
Diagram of the Colon and Rectum



Ongoing Flexible Sigmoidoscopy Randomized Trials

- United Kingdom, Atkin
  - Once only sigmoidoscopy
- Prostate, Lung, Colorectal,Ovarian, NCI
  - Sigmoidoscopy every 5 years with regular FOBT

Flexible Sigmoidoscopy: Evidence

- Case-control study (Selby, 1992)
  - 59% mortality reduction in cancers within reach of sigmoidoscope
  - No mortality reduction in proximal cancers
  - Primarily rigid sigmoidoscopes
- Case-control study (Newcomb, 1992)
  - 79% mortality reduction in cancers within reach of sigmoidoscope
  - Primarily flexible sigmoidoscopes

Flexible Sigmoidoscopy: Implementation

- Preparation
- Periodicity
- Provider capacity
- Follow-up
  - 5% to 15% will have a positive result
  - Positive result requires total colon exam
  - To biopsy or not?
    - Which provider?
    - Which lesions?
  - Negative result requires repeat flex sig in 5 years

To Begin an Office Flexible Sigmoidoscopy Screening Program

You will need

- Trained clinician(s)
- Equipment
  - Flexible sigmoidoscope
  - Light source
  - Suction device
  - Videoscreen preferable
- Procedure room with bathroom nearby
- Assigned roles for office staff
  - Patient scheduling and instruction
  - Equipment setup, cleaning, and maintenance
  - Assistance with procedure
- Informed consent policy

To Begin a Program of Referring to Another Facility for Flexible Sigmoidoscopy or Colonoscopy

You will need

- Identified partner site
- Mechanism for direct referral for the procedure
  - Includes pre-procedure testing and risk assessment

Flexible Sigmoidoscopy: Counseling Your Patients

- Patient education material
- Expect moderate discomfort (like gas pain)
- Most patients report that it's not as bad as they thought it would be
- Sedation not routinely used
- Exam lasts approximately 20 minutes
- Patients able to return to work and don't need a ride

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Flexible Sigmoidscopy + FOBT

- No randomized trial examining reduction in death using combination of tests
- Non-randomized trial (Winawer, 1992)
  - Sigmoidoscopy + FOBT vs. sigmoidoscopy alone-- RR for death 0.56

DCBE

- How it works
- No studies examining reduction in incidence or death using DCBE
- National Polyp Study (Winawer, 2000)
  - Substudy compared DCBE to colonoscopy
  - Study limited to post-polypectomy surveillance
  - Sensitivity of DCBE compared to colonoscopy
    - 32% for polyps <0.5cm
    - 53% for polyps 0.6-1cm
    - 48% for polyps >1cm

DCBE: Implementation

- Preparation
- Periodicity
- Provider capacity
- Follow-up
  - 5% to 15% will have a positive result
  - Positive result requires follow-up test, usually colonoscopy
  - Negative result requires repeat DCBE every 5 to 10 years

To Begin a Barium Enema Screening Program

You will need

- Identified experienced radiology site
- Assigned tasks for office staff
  - Patient education
  - Scheduling

DCBE: Counseling Your Patients

- Patient education material
- Expect moderate discomfort
- Requires patient to change position during exam
- Sedation is not used
- Exam lasts about 20 to 30 minutes
- Patient could return to work but will have frequent barium stools or constipation

Colonoscopy

- Most accurate single test for detection of cancer and/or polyps
- No prospective trials for effectiveness of screening colonoscopy
- Indirect evidence of efficacy from FOBT trials
- National Polyp Study supports effectiveness of polyp removal in cancer prevention
- Several colonoscopy feasibility studies ongoing in screening populations

Colonoscopy: Implemenation

- Preparation
- Periodicity
- Provider capacity
- Follow-up
  - Positive result frequently treated during screening exam
  - Negative result requires repeat colonoscopy in 10 years

Colonoscopy: Counseling Your Patients

- Patient education material
- Expect moderate discomfort with preparation, but actual procedure performed under sedation
- Some patients experience discomfort during recovery
- Exam lasts approximately 30 to 45 minutes
- Patient requires ride home after procedure and usually misses a work day

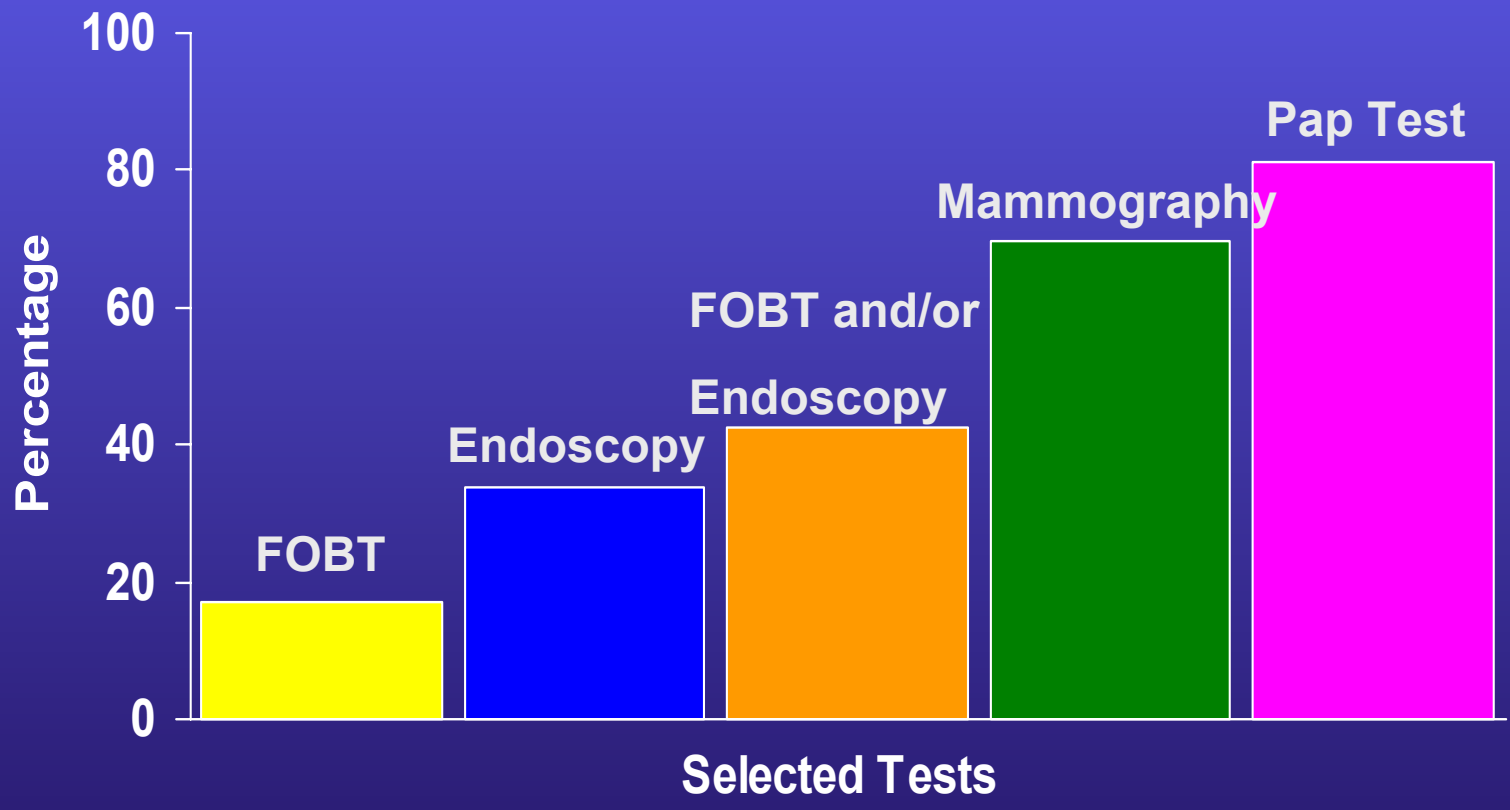
Digital Rectal Exam

- Not recommended as a stand-alone test for colorectal cancer screening
- Case-Control study (Herrinton, 1995)
  - No difference in screening history between cases and controls

Cost-Effectiveness (Cost/Year Life Saved)

♦ Mandatory motorcycle helmets	$2,000
♦ Colorectal cancer screening	$25,000
♦ Breast cancer screening	$35,000
♦ Dual airbags in cars	$120,000
♦ Smoke detectors in homes	$210,000
♦ School bus seat belts	$1,800,000

*Comparison of Colorectal Cancer Test Use with other Cancer Screening Tests, NHIS 2000**



* Among appropriate populations that receive screening tests

Choosing an Appropriate Screening Strategy

When Not To Screen

- Don’t apply screening guidelines to symptomatic patients
- Screening patients with terminal illness is unwarranted
- Benefits of polyp detection decrease with advanced age

Factors to Consider in Choosing a Strategy

- Patient's colorectal cancer risk
- Implementation issues
- Adverse effects
- Patient's preferences

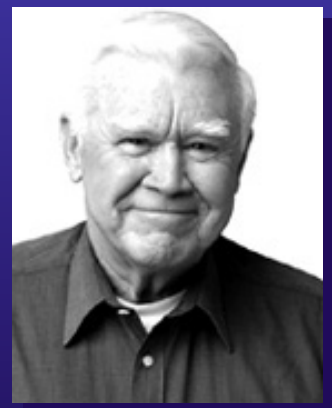
Assessing Individual Risk

- Increased risk includes:
  - personal history of colorectal cancer or polyps
  - family history of colorectal cancer or polyps
  - history of inflammatory bowel disease
  - certain inherited cancer syndromes
  - signs/symptoms
    - rectal bleeding
    - iron deficiency anemia
- Should undergo evaluation at an earlier age and more frequently

Assessing Individual Risk (continued)

Average Risk:

Everyone Else 50 and Over



Overarching Implementation and Counseling Issues

- Benefits and adverse effects
- Patient education materials
- Insurance coverage information
- Explicit policy and mechanisms for follow-up

New HEDIS measure on horizon

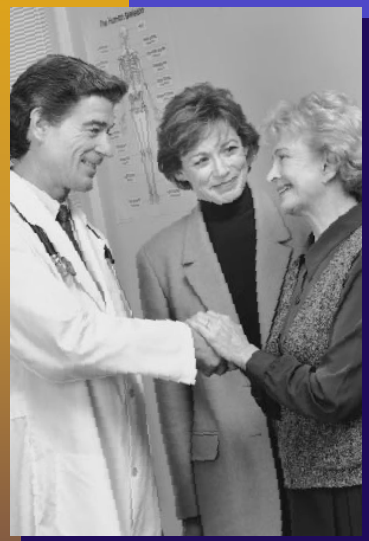
- Colorectal cancer screening measure provisionally approved
- Subject to results from public comment period in early 2003
- 2004 would be first year measure for HEDIS, based on performance in 2003

Potential Adverse Effects of Invasive Screening Tests

- Vasovagal syncope
- Perforation
- Hemorrhage

Estimated Costs of Colorectal Cancer Screening Options

♦ FOBT	$10 – $25
♦ Flexible sigmoidoscopy	$150 – $300
♦ Colonoscopy	$800 – $1600
♦ DCBE	$250 – $500



Shared Decision Making
vs.
Provider-Directed Choice

Outstanding issues

- Safety of tests
- Patient acceptability
- Cost
  - Health care coverage for patients
  - Reimbursement for health care providers
- Capacity to perform widespread screening

Future Screening Tests?

- Virtual Colonoscopy
- Stool DNA testing

Primary Prevention of Colorectal Cancer

- Exercise
- Low-fat diet rich in fruits and vegetables
- Fiber?
- Chemoprophylaxis
  - NSAIDs
  - Calcium
  - Estrogen
  - Folate
  - Selenium

A Call to Action

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